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APPLICATION NO.	FII	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,878	11/01/2000		Hiroshi Tamura	159-62	3533
23117	7590 05/18/2004			EXAMINER	
NIXON & '			соок,	COOK, LISA V	
8TH FLOOR	 {		ART UNIT	PAPER NUMBER	
ARLINGTO	N, VA 2	2201-4714	1641		

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## **Advisory Action**

Application No.	Applicant(s)	
09/702,878	TAMURA ET AL.	
Examiner	Art Unit	
Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCF) in compliance with 37 CFR 1.114

Examination (RCE) in compliance with 37 CFR 1.114.	
PERIOD FOR REPLY [check either a) or b)]	
a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on. (1) the mailing date of this Advisory Action, or (2) the date set forth event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing d ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF 706.07(f).	ate of the final rejection.
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CF have been filed is the date for purposes of determining the period of extension and the corresponding amount of 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally s (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final earned patent term adjustment. See 37 CFR 1.704(b).	of the fee. The appropriate extension fee under set in the final Office action; or (2) as set forth in
1. A Notice of Appeal was filed on Appellant's Brief must be filed within t 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismis	
2. The proposed amendment(s) will not be entered because:	
(a) $oxed{oxed}$ they raise new issues that would require further consideration and/or sear	rch (see NOTE below);
(b) ☑ they raise the issue of new matter (see Note below);	
(c) \( \sum \) they are not deemed to place the application in better form for appeal by issues for appeal; and/or	materially reducing or simplifying the
(d) they present additional claims without canceling a corresponding number	r of finally rejected claims.
NOTE: See Continuation Sheet.	*
3. Applicant's reply has overcome the following rejection(s):	
4. Newly proposed or amended claim(s) would be allowable if submitted in canceling the non-allowable claim(s).	a separate, timely filed amendment
5. ☑ The a) ☐ affidavit, b) ☐ exhibit, or c) ☑ request for reconsideration has been application in condition for allowance because: <u>See Continuation Sheet</u> .	considered but does NOT place the
6. The affidavit or exhibit will NOT be considered because it is not directed SOLI raised by the Examiner in the final rejection.	ELY to issues which were newly
7.⊠ For purposes of Appeal, the proposed amendment(s) a)⊠ will not be entered explanation of how the new or amended claims would be rejected is provided	• • •
The status of the claim(s) is (or will be) as follows:	
Claim(s) allowed: NONE.	
Claim(s) objected to: NONE.	
Claim(s) rejected: <u>10-23</u> .	
Claim(s) withdrawn from consideration:	
8. $\square$ The drawing correction filed on is a) $\square$ approved or b) $\square$ disapproved	I by the Examiner.
9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(10. Other:	(s)
	LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

## cantinuation Sheet (PTOL-303) 009/702,878

Continuation of 2. NOTE: Independent claim 10 has been amended to recite the separate analysis of known and unknown concentrations of CRP. However the claims previously read on the detection of either the unknown or known concentrations. Thus the newly recited claims set forth new issues that must be re-considered with respect to the prior art. Although the claims are read in light of the disclosure, limitations from the disclosure are not read into the claims. Applicant contends that the Examiner has indicated 112, 2nd deficiencies of claim 10 in paragraph A on page 5 of the Office Action dated January 14, 2004 (Paper #14). However, this rejection did not require the addition of new matter. Specifically the disclosure must support assays wherein separate steps invoving sample contacted for unknown concentrations of CRF and a control contact with known concentrations of CRP to produce a correlative determination of CRP concentration in the sample. The disclosure teaches a method measuring the concentration of CRP in a sample without known concentrations on page 14 line 11 through page 15 line 9 (figures 1B and 1C). Applicant is invited to show support for the new limitations (separate analysis of control solutions correlated to the unknown sample), absence such support the new claims are deemed new matter and will not be entered.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's request for reconsideration is acknowledged. However upon reconsideration the arguments were not found persuasive. Applicant contends that the cited art does not teach the instant invention because although teaching PC binding they may or may not incorporate the use of a second antibody to CRP while the instant invention only requires a single antibody. In response it is noted that the claims use the open language - term "comprising" and therefore reads on methods including more than what's recited in the claims. Further distinctions regarding detection senstitivity and advantages are not included in the claims. Therefore the rejections of record are maintained.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571)

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone

number is (571) 272-1600.

Lisa V. Cook Patent Examiner Remsen 3C-59 (571) 272-0816

4/28/04